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EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,538	LEUNG ET AL.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,9-16 and 18-22* is/are pending in the application.

4a) Of the above claim(s) *15,16,18 and 19* is/are withdrawn from consideration.

5)☒ Claim(s) *22* is/are allowed.

6)☒ Claim(s) *3, 4, 9-14, 20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The applicant has timely traversed the non-final rejection in the reply filed on 11/09/2006, and a response to the arguments is set forth.

2. Claims 3, 4, 9 and 12 have been amended.

3. Claim 22 has been newly added.

4. Claims 3, 4, 9-14, 20, 21 and 22 are under examination.

5. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior office action.

6. This office action consists of new grounds of rejections.

Objections Withdrawn

7. The objection of the specification as stated in paragraph 5 of the previous office action mailed on 07/10/2006 is withdrawn in view of amendments to the specification.

Rejections Withdrawn

8. The rejection of claims 9-14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of amendments to the claims.

9. The rejection of claims 3 and 4 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding a chimeric anti-idiotype antibody or fragment thereof, wherein said antibody or fragment thereof

specifically binds to the idiotype region of an anti-CEA monoclonal antibody comprising all of the rW12 heavy and light chain variable regions as set forth in SEQ ID NOs:1, 2 and 3 and SEQ ID NOs:4, 5, and 6 respectively, does not reasonably provide enablement for an anti-idiotype antibody which does not contain a full set of six CDRs is withdrawn in view of amendments to the claims.

10. The rejection of claims 9-14 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of amendments to the claims.

New Grounds of Rejections

11. Claims 3, 4, 20 and 21 are vague and indefinite in the recitation of "rWI2" as the sole means of identifying the expressed gene referred to in claims 20 and 21. The use of laboratory designations to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules.

Amending the claims to specifically and uniquely identify rWI2, for example, by SEQ ID NO can obviate this rejection.

12. Claims 9-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163 does state that for a generic claim the genus can be adequately described if the disclosure

presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

In the instant case, the claims are drawn to an isolated expression vector comprising a first nucleic acid sequence that encodes a WI2 heavy chain and a second nucleic acid sequence that encodes a WI2 light chain.

The specification teaches that rWI2 is a rat anti-idiotype antibody against an anti-carcinoembryonic antigen antibody (MN-14). In addition hWI2 is disclosed, wherein the FR rat regions of rWI2 are replaced by the human IgG counterpart; and chimeric (CWI2) is disclosed (paragraphs 51-53, in particular). The specification also discloses the amino acid sequences for rWI2 and hWI2. Further, Fig. 5 shows a comparison between hWI2(RS), hWI2, cWI2, and rWI2 in competitive binding assays; Fig.6 and Fig.7 show the nucleic acid sequence for the variable region of rWI2 light and heavy chain, respectively.

The specification does not teach various other forms of WI2 and is silent about the variants and/or any other forms of WI2 as encompassed by the claims. The specification provides the design of hVh and hVk by aligning the rVh and rVk in figures 1, 2 and 3; in addition to showing the comparison between hWI2, cWI2, and rWI2 in competitive binding assays in figure 5. However, the specification neither discloses a general antibody, WI2 as claimed, nor does it provide any information as to what WI2 is and if it is well known in the art. Also, the specification does not teach any SEQ ID NO for WI2. Thus, the specification does not provide specific guidance that would enable one skilled in the art to make and use the invention without undue experimentation. The specification does not disclose the extremely large number of Vh and Vl broadly encompassed by the claims.

It is known in the art that WI2 is an anti-idiotypic antibody against an anti-carcinoembryonic antigen antibody (MN-14). However, the amino acid sequence (framework region and CDRs) and the structure of WI2 and various forms (cWI2, rWI2

and hWI2) as claimed are not known. Thus, neither the specification nor the relevant art revealed any specific sequence for a WI2 anti-idiotypic antibody as claimed. Thus, the physical and chemical properties, including the defined functional properties and the methods of preparation, of the various forms of WI2 encompassed by the claims are not disclosed in the specification.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad genus. Claims 9, 10, 12 and 14 are broadly generic to all possible WI2 anti-idiotypic antibodies encompassed by the claims. The possible variations are enormous to any class of anti-idiotypic antibodies. Since the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of WI2 alone beyond those disclosed in the examples in the specification, which pertain to hWI2, cWI2 and rWI2. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of any WI2 other than hWI2, cWI2, and rWI2.

While having written description of hWI2, cWI2, and rWI2 identified in the figures of the specification, the specification is devoid of any other WI2 that qualify for the

functional characteristics claimed. The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Allowable Subject Matter

13. Claim 22 is allowed.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
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Ph: (571) 272-8789

SHEELA HUFF
PRIMARY EXAMINER